INNOVATIVE GLOVES CO., LTD.
Sanambin-BanKlang Rd., Tambon Kuanlang, Amphur Hatyai, Songkhla 90110 THAILAND.
TEL: (66) 7424 0132, 424 0185, 7424 0195 FAX: (66) 7424 0233, 7447 4734

MAR 6 2009

K083908

# Summary of Safety And Effectiveness

## A. Information

1. Submitter's

| | |
|---|---|
| Name: | Innovative Gloves Company Limited. |
| Address: | 830 Moo 4, Sanambin –Banklang Road<br>Kuanlang, Hatyai, Songhkla 90010, THAILAND |
| Telephone Number:<br>Fax | (6674) 240132, 240195 ,<br>(6674) 240233, 474734 |
| Contact person: | Mr. Rajeev Sood |

2. Name of Device

| | |
|---|---|
| Trade Name: | Nitrile Examination Gloves Powder-Free (Black Color).<br>**510K Number: K083908** |
| Device Class: | Class I |
| Device Name: | Patient examination gloves - 21 CFR 880.6250 Device<br>Black Nitrile Powder free Examination Gloves |

3. Predicate Device: Nitrile Examination Glove Powder-Free
510K Number: K993325

4. Description of device
Black Nitrile Powder-Free Medical Examination
Glove is a disposable device intended for medical purposes; that is worn on the examiner's hand, to prevent contamination between the patient and examiner.

5. Statement of intended use,
This is a disposable device intended for medical purposes that is worn on the examiners hands to prevent contamination between the patient and the examiner.
Powder-Free examination gloves are suitable in situations where powder is not desirable.

6. Explanation of similarities or differences to predicate device
The proposed device is identical to the predicate device except for the following:
The proposed device has been rendered black instead of natural color (510K Number: K993325)

**INNOVATIVE GLOVES** CO., LTD.
Sanambin-BanKlang Rd., Tambon Kuanlang, Amphur Hatyai, Songkhla 90110 THAILAND.
TEL: (66) 7424 0132, 424 0185, 7424 0195 FAX: (66) 7424 0233, 7447 4734

**B) Performance**

| Non-Clinical Tests | Standard | Performance |
|---|---|---|
| Dimensions | ASTM D 6319-00a | Meets |
| Physical Properties | ASTM D 6319-00a | Meets |
| Freedom from pinholes | ASTM D 6319-00a | Meets |
| Powder Free | ASTM D 6319-00a | Meets |

| Clinical Tests | Standard | Performance |
|---|---|---|
| Skin Irritation Study | ISO 10993, Part 10:2002(E) | Meets |
| Skin Sensitization Study | ISO 10993, Part 10:2002(E) | Meets |

**C) Conclusion**

The Nitrile Examination Gloves Powder-Free (Black Color) has been carefully compared to a legally marketed device in the 510(k). The data summaries indicate that the proposed product meets or exceeds accepted scores for the predicate product in both physical and nonclinical tests and satisfies the requirements for a safe and effective powder free medical glove.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Rajeev K. Sood
President & CEO
Innovative Gloves Company, Limited
830 Moo 4, Sanambi-Ban Klang Road
Kuanlang, Hatyai
Songkhla 90110
THAILAND

MAR 6 2009

Re: K083908
Trade/Device Name: Nitrile Examination Gloves Powder-Free (Black Color)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: February 17, 2009
Received: February 17, 2009

Dear Mr. Sood:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INNOVATIVE GLOVES CO., LTD.
830 Moo4, Sanambin-BanKlang Road. Kuanlang, Hatyai, Songkhla 90110 THAILAND.
TEL: (66) 7424 0132, 424 0185, 7424 0195 FAX: (66) 7424 0233, 7447 4734

# Indications for Use

510(k) Number (if known): K083908

Device Name: Nitrile Examination Gloves Powder-Free (Black Color).

A powder free patient examination glove is a disposable device made of synthetic Nitrile butadiene rubber later material may bear a trace of glove powder and is intended to be worn on the hand for medical purposes to provide a barrier against potentially infectious material and other contaminants.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083908